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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,480	11/15/2005	Henry Nicolas Jabbour	20747/210	6559

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Edwin V Merkel
Nixon Peabody
Clinton Square
P O Box 31051
Rochester, NY 14603

EXAMINER	
SZNAIDMAN, MARCOS L	
ART UNIT	PAPER NUMBER
4173	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,480	JABBOUR ET AL.	
	Examiner	Art Unit	
	MARCOS SZNAIDMAN	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,9,12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,9,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 2, 6-8, 10-11 and 14-31 have been cancelled, in the reply filed on December 14, 2007.

Claims 1, 3-5, 9 and 12-13 are currently pending and are the subject of this office action.

Claims 1, 3-5, 9, and 12-13 are presently under examination.

Applicant's amendment of claims 1, 9, 12 and 13, in the reply filed on December 14, 2007 is acknowledged.

Priority

The present application is a 371 of PCT/GB03/01521 filed on 04/10/2003, which claims priority to foreign application: United Kingdom 0208785.6 filed on 04/17/2002.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). See, for example, Table 1 on page 8, examples 7-18; and lines 20 and 21 on page 29. However, this application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statements under 37 CFR §§ 1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given

the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Response to Arguments

This is in response to applicant's arguments, filed on December 14, 2007

Claims rejected under 35 USC 101

Applicant's arguments have been fully considered and are persuasive.

Claims 14-18 have been cancelled by applicant.

Rejection under 35 USC 101 is withdrawn.

Claims rejected under 35 USC 112 (written description).

Applicant's arguments have been fully considered and they are persuasive.

Rejection under 35 USC 112 (written description) is withdrawn.

Claims rejected under 35 USC 112 (enablement)

Applicant's arguments have been fully considered but they are not persuasive.

By removal of the word preventing form claims 1, 3-5, 9, and 12-13, applicant was able to overcome the first part of the enablement rejection.

However, applicant argues that the specification provides enough data to overcome the second part of enablement rejection. Applicant refers to example 1, where studies show that "the FP receptor is expressed in human endometrium and endometrial adenocarcinoma. More particularly, a significantly increased expression of

FP receptor mRNA was observed in mid- to late-proliferative tissue that was increased further in endometrial adenocarcinomas (page 24, lines 17 to 22 of the specification). FP receptor expression in human endometrium demonstrated a distinctive localization pattern across the cycle, with the FP receptor being localized to glandular epithelial cells in only mid- and late-proliferative stages of the menstrual cycle (page 31, lines 9 to 12), and in uterine adenocarcinoma biopsies, FP receptor expression was localized to epithelial cells and was observed in all differentiation types with no discernible change in pattern between poor, moderately or well differentiated samples (page 31, lines 13 to 17 of the specification)". All these arguments only prove that the FP receptor might play a role in the diseases of the uterus claimed by applicant (uterine cancer, fibroids and endometriosis), and definitively is an invitation for further research in this area. However, these arguments do not demonstrate at all that an FP receptor antagonist could treat any of these diseases. There is no *in-vitro* or *in-vivo* clinical data and/or proof of mechanism in the instant application and in the litaerature of any kind to suggest that an FP antagonist might be useful in the treatment of uterine cancer, fibroids and endometriosis. For these reasons, one skilled in the art could not use the invention without undue experimentation.

Since claims 1, 9, 12 and 13 have been amended to include the limitation: "having a pathological condition of the uterus associated with abnormal growth of cells of the myometrium or endometrium", they now are also included in the enablement rejection.

Rejection under 35 USC 112 (enablement) is maintained.

Claims rejected under 35 USC 112 (second paragraph)

Applicant's arguments have been fully considered and are persuasive.

Claims 14-18 have been cancelled by applicant.

The rejection of claims 1, 9 and 12-13 for indefiniteness of the language "pathological condition of the uterus" is overcome by the amendments.

The rejection of claims 1, 9 and 12-13 for failing to disclose the full meaning of the abbreviations: PGF2 alpha, FP, PGES, EP2 and EP4 is overcome by the amendments.

Finally, the rejection of claim 13, regarding the indefiniteness of the term "IFTSYLECL" is overcome by the amendments.

Rejection under 35 USC 112 (second paragraph) is withdrawn.

Claims rejected under 35 USC 102 (e)

Applicant's arguments have been fully considered and are persuasive.

The 102 (e) rejection of claims 1, 9 and 12-13, as being anticipated by Sharif et. al. (US 6,441,033) is now overcome by the amendments.

Rejection under 35 USC 102(e) is withdrawn.

Claims rejected under 35 USC 103

Applicant's arguments have been fully considered and are persuasive.

The 103 rejection of claims 1, 9 and 12-13, for obviousness over Chemtob (US 6,300,312) in view of Sharif et. al. (US 6,441,033) is now overcome by the amendments.

Rejection under 35 USC 103 is withdrawn.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-5, 9, and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1, 3-5, 9, and 12-13, recite methods for treating a pathological condition of the uterus (uterine carcinoma in claim 3, endometriosis in claim 4, fibroids in claim 5) in a female individual, the method comprising administering to the individual an

antagonist of the FP receptor. However the claims are too broad in terms of the compounds claimed: any FP antagonist, and there is no proof of mechanism and experimental data to support that any FP antagonist could treat a condition of the uterus associated with abnormal growth of cells of the myometrium or endometrium. For example: examples 2 (treatment of uterine cancer with FP receptor antagonist), 5 (treatment of fibroids with FP receptor antagonist) and 8 (treatment of endometriosis with FP receptor antagonist) recite a method of treating patients suffering from: uterine cancer (example 2), fibroids (example 5) and endometriosis (example 8), but fail to give any results that demonstrate that after these treatments the patients recovered and/or benefited from these treatments. There is also no in *vivo* or *in vitro* data of any kind to prove the mechanism of action of the FP receptors in treating a condition of the uterus associated with abnormal growth of cells of the myometrium or endometrium. The only data that applicant provides is the presence and over expression of FP receptors in the uterus under the conditions associated with those diseases. All these arguments only prove that the FP receptor might play a role in the diseases of the uterus claimed by applicant (uterine cancer, fibroids and endometriosis), and definitively is an invitation for further research in this area. However, these arguments do not demonstrate at all that an FP receptor antagonist could treat any of these diseases. There is no evidence in the prior art that FP antagonists have any effect on patients with the above-described conditions, and since applicant does not provide any evidence of the effectiveness of these compounds or the mechanism of action to treat a condition of the uterus associated with abnormal growth of cells of the myometrium or endometrium, the result

of examples 2, 5 and 8 are unpredictable. For this reason, one skilled in the art could not use the invention of claims 1, 3-5, 9, and 12-13, without undue experimentation.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MLS

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614